REMARKS

Applicant has not added, cancelled, or amended claims herein.

Rejection Under 35 U.S.C. §112, Written Description

In the March 26, 2010 Office Action issued in connection with the above-identified application the Examiner continued to maintain the rejection of claims 89-105 as allegedly containing subject matter not described in the specification so as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner stated that "[t]he application [has a] single example of [a] tablet which is composed of 2.5mg of oxandrolone, and [a] specific amount of corn starch, hydrous lactose, hydroxypropyl methylcellulose, and magnesium stearate." The Examiner further stated that "[t]he application merely mentions [a] 10-milligram dose, but does not disclose any further information as to the carrier and particular forms." From this the Examiner concluded that "[t]herefore the application as originally filed, [lacks] support of a unit dosage form, or tablet comprising 10 mg of oxandrolone, and one or more of the corn starch, hydrous lactose, hydroxpropyl methylcellulose, and stearate, nor to the particular amounts of the carriers."

Applicant initially notes that the Examiner's written description rejection as presently stated is not properly germane to independent claim 88 which does not recite the specific carriers referred to by the Examiner. Nevertheless, insofar as the Examiner has rejected all pending claims on this ground, applicant notes the following. MPEP 2163(II)(A) requires the Examiner to "explain why persons skilled in the

art would not recognize in the disclosure a description of the invention defined by the claims." The Examiner has not met this requirement. In fact the Examiner acknowledged that the application "mentions" the 10mg dose form, but is not specific in regard to merely the particular carrier(s). However, the notion that one skilled in the art, for example a doctor administering oxandrolone or a pharmaceutical scientist, would somehow require a specific formulation listing of carrier ingredients and types for the specific 10mg oxandrolone form to understand that applicant was in possession of a solid pharmaceutical composition in 10mg unit dose form comprising a pharmaceutically acceptable carrier and 10 mg of oxandrolone is not tenable. The specification only need reasonably convey to one skilled in the art the claimed invention.

Applicants also note that the "absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, para. 1, for lack of adequate written description", see MPEP 2163(II)(A)(1). "Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement", see MPEP 2163(II)(A)(2). In this regard, tablet formulation and combination of active ingredients with pharmaceutically acceptable carriers were well-established at the time of filing.

Applicant herein re-states some of the support found in the published specification for the claimed invention:

> "[0011] Oxandrolone disposition and metabolism in man has been studied following oral administration of a 10 milligram dose. The study indicated that oxandrolone was rapidly and completely absorbed, yielding a mean peak

plasma concentration of 417 micrograms of oxandrolone per milliliter at 66 minutes. The plasma concentration of oxandrolone declined in a biphasic manner with a distribution half-life of approximately 30 minutes and an elimination half-life of 9.4 hours. Protein binding of oxandrolone was observed to be extensive." (emphasis added)

"[0016] For purposes of administration in accordance with this invention, the active ingredient oxandrolone is combined with solid or liquid pharmaceutical carriers and formulated in unit dosage form using pharmacologically acceptable excipients, or dissolved or suspended in physiologically acceptable solvents or liquid vehicles for oral, percutaneous, or topical administration." (emphasis added)

"[0017] The overall daily dose of oxandrolone to provide a therapeutically effective amount in accordance with the method of this invention can be as low as about 2.5 milligrams and as high as about 20 milligrams, depending upon the patient's response and the mode of administration."

"[0021] The route of administration can be oral, percutaneous, transdermal, sublingual, buccal, intravenous, intramuscular, or the like. Of these, oral administration is preferred. The patient's daily dose of the active ingredient preferably is in the range of about 7.5 milligrams, but may exceed 20 milligrams based on clinical response. This daily dose can be given in tablet form as a single dose, or as plural divided doses, preferably 2 to 3 divided doses. The requisite daily dose can also be supplied continuously, for example, by a

transdermal patch worn by the patient or intravenously. If the oxandrolone is administered orally, dosages in the range of about 2 to about 5 milligrams three to four times daily typically may be utilized." (emphasis added)

In view of the support in the specification and the stated standard for complying with the written description requirement, it is not tenable to maintain that the specification does not reasonably convey to one skilled in the art the claimed "unit dosage form comprising a pharmaceutically acceptable carrier and 10 mg of oxandrolone per unit dosage form". The applicant therefore requests withdrawal of this ground of rejection.

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 88-105 under 35 U.S.C. §103(a) as allegedly obvious over Metcalf et al. (of record) in view of ANAVAR® (of record) and Babu et al. (U.S. Patent No. 5,073,380) and "further in view of applicant's admission at page 7."

Applicant maintains that the invention as claimed is not obvious over the cited art.

1) *Applicant was first to identify the issue that provided the motivation to create a 10mg unit dose form*

a) Applicant was the first to identify oxandrolone as a treatment for AIDS symptoms

Prior to applicant's invention as disclosed in the present application, it was not known that oxandrolone could be used to treat certain symptoms of AIDS and side effects of AIDS therapy such as HIV-associated myopathy, muscle weakness and

muscle wasting.

b) AIDS patients have high pill burdens due to polypharmacy treatments, which results in patient compliance issues

AIDS patients are often treated in the clinic with a polypharmacy approach to counter the various symptoms of AIDS as well as the side effects of the AIDS treatments themselves. This results in art-recognized pill burden issues for AIDS patients and HIV-positive patients leading to compliance and adherence problems (e.g. see **Exhibit A** at page 281, "Pill Burden Key To Doing Well"; Brook et al., and **Exhibit B** at page 136 "Daily Pill Burden and Adherence").

c) Prior to applicant's identification of oxandrolone as a treatment for AIDS symptoms, there was no motivation to make unit dose forms of oxandrolone greater than the 2.5mg unit dose form already available

Oxandrolone had been manufactured only in a 2.5mg unit dose form since the early 1960s (e.g. see Anavar® Physician's brochure). Prior to applicant's discovery of the use of oxandrolone in treating AIDS patients, and thus prior to the identification of a specific pill burden issue with respect to oxandrolone, there existed no motivation to make a unit dose form comprising 10mg oxandrolone. However, *after* identification of oxandrolone as a treatment for AIDS symptoms consideration of the problem of pill burden arose. This previously unidentified problem is addressed by applicant's claimed unit dose form containing 10mg oxandrolone.

Because there was no pill burden problem identified for oxandrolone prior to applicant's invention, there was no motivation to make a unit dose form comprising 10mg oxandrolone at the effective filing date, and consequently the invention as claimed is not obvious over the cited art.

Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

2) *The Examiner has used impermissible hindsight to specifically select a unit dose form comprising 10mg oxandrolone*

Were hindsight appropriate, it would be possible to make up any convenient regimen to arrive at the claimed invention. However, there is no rationale of record based on the cited art for a 10mg unit dose form. The only recitation of a 10mg dose is not as a unit dose form (see Metcalf et al.). Importantly, Metcalf et al. teaches that the 10mg dose is not effective (see left hand column of Abstract and page 60 of Metcalf et al.). Thus, the 10mg unit dose form is being "created" by the Examiner without any rationale based on prior art; the art cited by the Examiner in fact teaches away from a 10mg unit dose form. For this reason alone, the rejection is improper. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In compliance with his duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following items, which are listed on the accompanying Form PTO-1449 (Substitute) as **Exhibit C**, and copies of which are attached hereto as **Exhibits 1-3**.

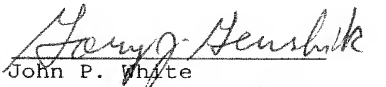
1. Office Action issued September 28, 2010 in connection with U.S. Serial No. 11/726,105; **(Exhibit 1)**
2. Office Action issued October 27, 2010 in connection with U.S. Serial No. 10/799,197 **(Exhibit 2)**; and
3. Final Office Action issued October 6, 2010 in connection with U.S. Serial No. 10/799,264 **(Exhibit 3)**

This Supplemental Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(b)(4). The Examiner is respectfully requested to make the listed items of record in the present application by initialing and returning a copy of the enclosed Form PTO-1449 (Substitute).

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the total enclosed fee of $470.00, including $65.00 for a one-month extension of time and $405.00 for filing an RCE, is deemed necessary with the filing of this Communication and Supplemental Information Disclosure Statement and accompanying RCE. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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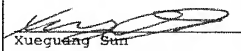

Xueguang Sun — Date 12/22/2010